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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,614	01/12/2001	Francis Darro	P66243US0	6005

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EXAMINER
COOK, REBECCA

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/22/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,614

Applicant(s)

DARRO ET AL.

Examiner

Rebecca Cook

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 16-24 are is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

In view of the following rejections, the Final Rejection of 4/10/03 is withdrawn.

Claims 9-11 are withdrawn as being drawn to a non-elected invention.

Applicants' elected the enhanced combination of genistein and vincristin for examination on the merits. Claims 16-24 are being examined as they read on the elected combination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-24 are again are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating, does not reasonably provide enablement for preventing or reducing the risk of cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to a method for treating a tumor using a combination comprising genistein and vincristin.

2) State of the prior art.

Cancer therapy remains highly unpredictable and no examples exist for efficacy of the combination against all tumors.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. There are a vast number of tumors and no one combination is used to treat all tumors

4) Level of predictability in the art.

The art pertaining to the treating tumors remains highly unpredictable. No examples exist for efficacy of the elected combination against all tumors.

5) Amount of direction and guidance provided by the inventor.

Applicants contemplate the instant combination, but do not disclose data only in Tables III and IV for genistein and three cytotoxic agents. In Table IV, treatment 5, the

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combination of genistein and cyclophosphamide (CPA) yields a smaller decrease in tumor growth than CPA alone.

6) Existence of working examples.

Applicants' claims are broad, but the specification contains working examples demonstrating the efficacy of the combination of genistein and CPA, vincristine (VCR) and etoposide (ETO) against murine mammary adenocarcinoma (HS-MXT). It is noted that in Table IV, treatment 5, the combination of genistein and cyclophosphamide (CPA) yields a smaller decrease in tumor growth than CPA alone.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible tumor disorders and cytotoxic compounds included in the recited method.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The skilled artisan would have to screen against an infinite amount of tumors using many cytotoxic agents in combination with an isoflavonoid in order to determine which ones the combination could be used to treat tumors.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975.

Applicants' argument that each of the cytotoxic agent assayed pertains to a different class of cytotoxic agents is not persuasive, since Tables III and IV do not

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contain an example from all classes of cytotoxic drugs and the data in Table IV, treatment 5, shows that the combination of genistein and cyclophosphamide (CPA) yields a smaller decrease in tumor growth than CPA alone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al in view of WO 97/46531 for the reasons given in Paper No. 9.

Applicants' argument that one skilled in the art could not have expected that isoflavonoids would potentiate cytotoxicity of conventional cytotoxic agents is not persuasive, since a potentiating cytotoxicity effect is not recited.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-37 of allowed of copending Application No. 09/743,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of '676 renders obvious the instant method of treating a tumor using a cytotoxic agent and isoflavonoid.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200 1614

January 20, 2004